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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,229	01/20/2000	Edward H. Cully	MP/140A	4139
7590	01/30/2004		EXAMINER	
Wayne D House W L Gore & Associates Inc 551 paper Mill Road P O Box 9206 Newark, DE 19714-9206			BUI, VY Q	
			ART UNIT	PAPER NUMBER
			3731	
			DATE MAILED: 01/30/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/488,229	CULLY ET AL. <i>J.P.</i>	
	<b>Examiner</b>	<b>Art Unit</b>	
	Vy Q. Bui	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 November 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-47 is/are pending in the application.
  - 4a) Of the above claim(s) 8,20,21,26,27,34,40,41,46 and 47 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7,9-19,22-25,28-33,35-39 and 42-45 is/are rejected.
- 7) Claim(s) 15 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Species I (Fig. 1A-1H) in Paper No. 6 is acknowledged.

Claims 8, 34, 47 (Fig. 4, species 4), 20-21(Fig. 3, species 3), 26-27, 40-41, 46 (Fig. 2, species 2) are withdrawn from further consideration. However, upon the allowance of a generic claim, claims read on species dependent to the allowed generic claim will be allowed as well.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 recites the limitation "the thermoplastic fluoropolymer" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3731

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-33, 36-39 are rejected under 35 U.S.C. 102(e) as being anticipated by LEOPOLD et al (6,352,561).

The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

LEOPOLD (Fig. 3; col. 11, ll. 4-65) discloses nitinol stent 126 and cover 124 of ePTFE joined together by adhesive FEP, which adhesive can render the cover 124 non-porous (col. 11, ll. 39-44).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3731

1. Claims 1-7, 9-12, 13-19, 22-24, 35 are rejected under 35 U.S.C. 103(a) as being obvious over LEOPOLD et al (6,352,561) in view of LAU et al. (5,735,893).

The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

As to claims 1-7, 9-11, 13-19, 22-24, 35, LEOPOLD (Fig. 3; col. 11, ll. 4-65) discloses nitinol stent 126 and cover 124 of ePTFE of a thickness about 0.1 mm (col. 11, ll. 45-47) joined together by adhesive FEP, which adhesive can render the cover 124 non-porous (col. 11, ll. 39-44) and substantially every limitation in the claims,

except for the stent has apices protruding outwardly to anchor to a wall vessel and the stent foreshortens less than 10 % when expanded. LAU (Fig. 4, 13-14; col. 3, ll. 3-7) discloses a stent structure including outwardly protruding apices 34 for anchoring the stent to a blood vessel wall and interconnecting member 13 for avoiding foreshortening of the stent. In view of LAU, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify or construct LEOPOLD stent to have outwardly protruding apices and to have a foreshortening percentage less than about 10%.

As to claim 12, the coating processes as recited in the claim are well known coating processes in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the processes to make a coating on the covering.

As to claim 25, LEOPOLD discloses substantially every limitation in the claims, except for the thickness of the cover 124 less than 0.05mm. However, ePTFE cover of thickness less than 0.05mm for low profile of a stent-graft during deployment is well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the cover of a thickness less than 0.05mm for low profile during the stent-graft deployment.

As to claims 28-31 and 42-45, LEOPOLD discloses substantially every limitation in the claims, except for the liquid impermeability of the cover as recited in the claims. It is well known to make a cover of a biliary stent-graft impermeable to bile fluid and the

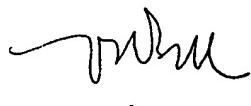
bubble test pressures as recited in the claims are just another indicator to express the inherent characteristics of a conventional cover for a biliary stent-graft.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



VQB  
1/23/2004.